

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MINNESOTA

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CHRISTINA KNIPP, )  
                        )  
Plaintiff,           )      CASE NO. \_\_\_\_\_  
                        )  
                        )  
v.                     )  
                        )  
BAYER HEALTHCARE     )      COMPLAINT AND JURY DEMAND  
PHARMACEUTICALS INC., )  
                        )  
                        )  
Defendant,            )  
                        )

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Plaintiff, by and through counsel, and for her Complaint against Defendant, alleges as follows:

**PARTIES AND CITIZENSHIP**

1. Plaintiff is a resident and citizen of Richland County, Ohio.
2. Plaintiff was prescribed and used the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant.
3. Defendant Bayer Healthcare Pharmaceuticals Inc. ("Bayer") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer can be served at 67 Whippny Road, Whippny, NJ 07981.
4. Defendant Bayer Healthcare Pharmaceuticals Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

5. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals Inc.

6. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application (NDA) for contraceptive device Mirena®.

7. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena®.

8. Bayer does business in the state of Minnesota through the sale of Mirena® and other prescription drugs in the state.

9. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

#### **JURISDICTION AND VENUE**

10. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

11. Venue in this Court is proper in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell and market the Mirena® within Minnesota and nationwide.

## **FACTUAL ALLEGATIONS**

12. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

13. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as a contraceptive.

14. The federal Food and Drug Administration (FDA) approved Defendant's New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

15. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendant admits it is not known exactly how Mirena® "works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

16. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

17. The package labeling recommends that Mirena® be used in women who have had at least one child.

18. Mirena®'s label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

19. Mirena®'s label also describes perforation as an "uncommon" event, despite the fact that there are numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

20. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

21. In or around December 2009, Bayer was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private settings by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendant.

22. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

23. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

24. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena®.

25. Finally, Defendant falsely claimed that Mirena® required no compliance with a monthly routine.

**CASE SPECIFIC ALLEGATIONS**

26. Plaintiff Christina Knipp is currently 28 years old.
27. Plaintiff had the Mirena® product (hereinafter sometimes "PRODUCT") inserted in or about June 6, 2011 by Women's Care, Inc. located in Mansfield, Ohio. Plaintiff tolerated the procedure well and Plaintiff did not have any reason to suspect that the Mirena® perforated her uterus.
28. Following the Mirena® insertion, Plaintiff conducted regular self-checks.
29. On or about April 26, 2012 a CT scan revealed that Plaintiff's Mirena® had perforated her uterus and was located in the intraperitoneal space. A follow-up x-ray confirmed the location of Plaintiff's Mirena® to be in the left mid-abdomen.
30. Plaintiff underwent a laparoscopic removal of her Mirena® on May 10, 2012, where Plaintiff's Mirena was found to be in her omentum in the left mid-quadrant.
31. Although Plaintiff followed all instructions accompanying the Mirena® and used the Mirena® as directed, after implant of the Mirena® Plaintiff suffered serious and life-threatening side effects and injuries, including but not limited to abdominal pain, surgical removal of her Mirena® and related sequelae requiring hospitalization, medical therapy, continuing treatment, and medical monitoring. Further personal injuries suffered by Plaintiff include, but are not limited to, pain and suffering, permanent bodily impairment, mental anguish and diminished enjoyment of life.
32. Plaintiff files this lawsuit within two (2) years of first suspecting that the Mirena® was the cause of appreciable harm sustained by Plaintiff, within two (2) years of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering their injuries and the wrongful conduct that caused such injuries. Plaintiff could not

by the exercise of reasonable diligence have discovered any wrongdoing, nor could Plaintiff have discovered the causes of her injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when Plaintiff's injuries were discovered, their causes were not immediately known.

33. Plaintiff did not suspect, nor did she have reason to suspect, that wrongdoing had caused her injuries, nor did Plaintiff have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the defects in the Mirena® and the wrongful conduct of Defendant as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of Defendant. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant herein misrepresented and continue to misrepresent to the public, to the medical profession and to Plaintiff that the Mirena® is safe and free from serious defects and side effects, and Defendant has fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

**FIRST CAUSE OF ACTION:**  
**DEFECTIVE MANUFACTURING**

34. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

35. At all relevant times, Defendant was engaged in the business of selling Mirena® in the State of Minnesota.

36. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant

was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

37. Defendant has introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena® outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena® caused serious harm to Plaintiff.

38. Defendant manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, its condition when sold was the proximate cause of the injuries sustained by the Plaintiff, and Defendant placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety,

39. As a direct and proximate result of Plaintiff's use of Mirena®, she developed excruciating pain, endured extreme suffering, and was forced to undergo surgical removal of the PRODUCT.

40. Defendant knew and, in fact, advertised and promoted the use of Mirena® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of Defendant's advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

41. Despite the fact that evidence existed that the use of Mirena® was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with the Mirena® and in fact acted to deceive the medical community and public at large, including all potential users of Mirena®, including Plaintiff, by promoting it as safe and effective.

42. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**SECOND CAUSE OF ACTION:**  
**DESIGN DEFECT**

43. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

44. At all relevant times, Defendant was engaged in the business of selling Mirena® in the State of Minnesota.

45. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

46. The foreseeable risks associated with the design or formulation of the Mirena® include, but are not limited to, the fact that the design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

47. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

48. As a direct and proximate cause of Plaintiff's use of Mirena®, she was forced to undergo surgical removal of the Mirena®, developed severe pain, suffered from infection, and underwent numerous procedures.

49. Defendant placed Mirena® into the stream of commerce with wanton and reckless disregard for public safety.

50. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

51. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

52. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**THIRD CAUSE OF ACTION:**  
**NEGLIGENCE**

53. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

54. Upon information and belief, Defendant failed to use reasonable care in designing Mirena® in that they:

- a. failed to properly and thoroughly test Mirena® before releasing the drug to market;
- b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;
- c. failed to conduct sufficient post-market testing and surveillance of Mirena®;

- d. designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. failed to exercise due care when advertising and promoting Mirena®; and,
- f. negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendant knew or should have known of its adverse effects.

55. A reasonable manufacturer would or should have known that the risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or in part for the increased risk.

56. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**FOURTH CAUSE OF ACTION:**  
**FAILURE TO WARN**

57. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

58. Mirena® is a defective and therefore an unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, uterine perforation post-insertion, or the possibility that device complications such as migration and perforation may cause abscesses, infections, require

surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

59. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold, and otherwise released into the stream of commerce the pharmaceutical, Mirena®, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

60. Mirena® was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

61. Defendant downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendant placed its profits above its customers' safety.

62. Mirena® was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it. Even though Defendant knew or should have known of the risks associated with Mirena®, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

63. Plaintiff used Mirena® as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

64. Plaintiff could not have discovered any defect in Mirena® through the exercise of reasonable care.

65. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field and, further, Defendant had knowledge of the dangerous risks and side effects of Mirena®.

66. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her physician(s).

67. Defendant had a continuing duty to warn consumers, including Plaintiff and her physicians, and the medical community of the dangers associated with Mirena®, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendant breached its duty.

68. Although Defendant knew, or was reckless in not knowing, of the defective nature of Mirena®, they continued to manufacture, design, formulate, test, package, label, produce, create, made, construct, assemble, market, advertise, distribute and sell Mirena® without providing adequate warnings and instructions concerning the use of Mirena® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena®.

69. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries as alleged herein, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**FIFTH CAUSE OF ACTION:**  
**STRICT LIABILITY**

70. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

71. Defendant is the manufacturer and/or supplier of Mirena® and is strictly liable to Plaintiff for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Mirena® into the stream of commerce.

72. Mirena®, manufactured and/or supplied by Defendant, was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

73. Mirena® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

74. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendant failed to adequately warn of these risks.

75. Mirena® was defective due to inadequate pre-marketing testing.

76. Defendant failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the extreme risks associated with Mirena® and continues to promote Mirena® in the absence of those adequate warnings.

77. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**SIXTH CAUSE OF ACTION:**  
**BREACH OF IMPLIED WARRANTY**

78. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

79. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® as safe for use by the public at large, including Plaintiff, who purchased Mirena®. Defendant knew the use for which its product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

80. Plaintiff reasonably relied on the skill and judgment of the Defendant, and as such its implied warranty, in using Mirena®.

81. Contrary to same, Mirena® was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

82. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**SEVENTH CAUSE OF ACTION:**  
**BREACH OF EXPRESS WARRANTY**

83. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

84. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® were expressly warranted to be safe by Defendant for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendant had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendant warranted Mirena® to be in all respects safe, effective and proper for such purposes.

85. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects.

86. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**EIGHTH CAUSE OF ACTION:**  
**NEGLIGENT MISREPRESENTATION**

87. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

88. Defendant, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena®, owed a duty to provide accurate and complete information regarding Mirena®.

89. Defendant falsely represented to Plaintiff that Mirena® was a safe and effective contraceptive option. The representations by Defendant were in fact false, as Mirena® is not safe and is dangerous to the health of its users.

90. At the time the aforesaid representations were made, Defendant concealed from healthcare providers and their patients, including Plaintiff and her physicians, information about the propensity of Mirena® to cause great harm. Defendant negligently misrepresented claims regarding the safety and efficacy of Mirena® despite the lack of information regarding same.

91. These misrepresentations were made by Defendant with the intent to induce Plaintiff to use Mirena®, which caused her injury.

92. At the time of Defendant's misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

93. Defendant breached its duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product. Plaintiff reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mirena®.

94. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**NINTH CAUSE OF ACTION:**  
**FRAUDULENT MISREPRESENTATION**

95. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

96. Defendant, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® described herein, owed a duty to provide accurate and complete information regarding Mirena®.

97. Defendant fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

98. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

99. Defendant knew this information to be false, incomplete and misleading.

100. Defendant intended to deceive and mislead Plaintiff so that she might rely on these fraudulent misrepresentations.

101. Plaintiff had a right to rely on and did reasonably rely upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

102. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**TENTH CAUSE OF ACTION:**  
**FRAUD BY CONCEALMENT**

103. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

104. Defendant had a duty and obligation to disclose to Plaintiff that Mirena® was dangerous and likely to cause serious health consequences to users when used as prescribed.

105. Defendant intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff with the intent to defraud her as herein alleged.

106. Neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

107. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

108. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ELEVENTH CAUSE OF ACTION**  
**VIOLATION OF THE OHIO CONSUMER PROTECTION ACT**

109. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

110. At all times relevant, O.R.C. § 1345.01, et seq., “prohibits a supplier from committing an unfair or deceptive act or practice related to a consumer transaction.”

111. Defendants violated the Ohio Consumer Protection Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Mirena®. Defendants communicated the purported benefits of Mirena® while failing to disclose the serious and dangerous side effects related to the use of Mirena® with the intent that consumers, like Plaintiff, and their healthcare providers rely upon the omissions and misrepresentations and recommend and use Mirena®, respectively.

112. As a result of violating the Ohio Consumer Protection Act, Defendants caused Plaintiff to be recommended and to use Mirena®, causing severe injuries and damages as previously described herein.

113. As a result of Defendants’ violations of the Ohio Consumer Protection Act, Plaintiff seeks damages and costs as provided by the Act.

**RELIEF REQUESTED**

WHEREFORE Plaintiff prays for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of the Plaintiff, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;
2. Past and future economic and special damages according to proof at trial;
3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;
5. Past and future pain and suffering damages, including mental and, emotional stress arising from Plaintiff's physical injuries, according to proof at the time of trial;
6. Equitable relief as requested and/or as the Court deems just and proper;
7. Declaratory judgment that Defendant is liable to Plaintiff for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendant's wrongdoing;
8. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;
9. Costs of suit incurred herein;
10. Pre-judgment interest as provided by law; and
11. Such other and further relief as the Court may deem just and proper.

**Plaintiff seeks a trial by jury on all issues.**

Respectfully Submitted,

**JOHNSON BECKER, PLLC**

Date: March 4, 2014

By: /s/ Michael K. Johnson

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